DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2015

Zavation, LLC
Mr. Lawrence Walker
Engineering Manager
400 Liberty Park
Flowood, Mississippi 39232

Re: K142392
Trade/Device Name: Zavation Posterior LEIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 27, 2015
Received: March 30, 2015

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142392

Device Name
Zavation Posterior LEIF

Indications for Use *(Describe)*
The Zavation Posterior LEIF(Lateral Expandable Interbody Fusion) implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation Posterior LEIF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended to be used in patients who have had six months of non-operative treatment.

The Zavation Posterior LEIF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Spinal System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K Summary

Date:	March 27, 2015
Submitter:	Zavation LLC 400 Liberty Park Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Lawrence Walker
Type of 510(k) submission:	Traditional
Trade name:	Zavation Posterior LEIF
Common name:	Intervertebral Body Fusion Device
Classification regulation:	21 CFR 888.3080 Intervertebral body fusion device
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	MAX
Basis for submission:	New device

Device Description:
The Zavation Posterior LEIF(Lateral Expandable Interbody Fusion) devices are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The implants are provided in a shape that accommodates a posterior or transforaminal approach to the lumbar spine. After insertion the implant can be expanded to a larger footprint. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These implants are to be filled with autogenous bone graft material. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

Intended Use:
The Zavation Posterior LEIF(Lateral Expandable Interbody Fusion) implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation Posterior LEIF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended to be used in patients who have had six months of non-operative treatment.

The Zavation Posterior LEIF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Spinal System.

Materials:
The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). And pins per titanium alloy (ASTM F136).

Predicate Devices:
Zavation IBF System (K120576) Primary
Vertebral Technologies InterFuse T (K110226)

Performance Data:
Mechanical test results demonstrated that the Zavation Posterior LEIF is substantially equivalent to the predicate devices. Testing was performed in accordance with:

- ASTM F2077, Test Methods for Intervertebral Body Fusion Devices
  - Static Axial Compression
  - Dynamic Axial Compression
  - Static Shear
  - Dynamic Shear
- ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM Draft F04.25.02.02, Static Pushout Test Method for Intervertebral Body Fusion Devices.

Comparison of Technological Characteristics:
The Zavation Posterior LEIF possesses the same technological characteristics as both predicates with one exception. They are the same in heights, lengths, widths, insertion method, and material construction. The one exception is that the footprint of the Zavation Posterior LEIF and the Vertebral Technologies InterFuse can both be expanded wider than their insertion width, but the Zavation IBF devices are only available in a fixed footprint.

Basis for Substantial Equivalence:
The Zavation Posterior LEIF devices are similar to the predicate systems with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacers to the predicate devices.